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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/840,341	04/23/2001	Adriano Aguzzi	30187/37275	2003

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EXAMINER

CARLSON, KAREN C

ART UNIT	PAPER NUMBER
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1653

DATE MAILED: 06/30/2003

5

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/840,341

Applicant(s)

AGUZZI ET AL.

Examiner

Karen Cochran Carlson, Ph.D.

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on ____.
- 2a) ☐ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-17 is/are pending in the application.
- 4a) Of the above claim(s) ____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) ____ is/are allowed.
- 6) ☐ Claim(s) ____ is/are rejected.
- 7) ☐ Claim(s) ____ is/are objected to.
- 8) ☒ Claim(s) 1-17 are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on ____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on ____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. ____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) ____.
- 4) ☐ Interview Summary (PTO-413) Paper No(s). ____.
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other: _____

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Claims 1-17 have been amended in the preliminary amendment filed April 23, 2001 (Paper #4). Claims 11-17 refer to factor that selectively binds PrPsc, PrPsc (see Claim 5 is drawn to a composition comprising PrPsc and the factor; thus the method claims can use one or the other), and a ligand that interacts with the factor. These are three different products because they differ in function and in structure and have been separated because they are patentably distinct products. Thus, some claims are repeated in different groups and these claims will be examined only in-so-far as they pertain to the elected subject matter. The Examiner notes that the claims are rather broad and she is open to reconsideration of the restriction requirement when the claims are further explained.

Restriction to one of the following inventions is required under 35 U.S.C. 121:

- I. Claims 1-9, 11, and 12, drawn to factor that selectively interacts with PrPsc and not PrPc classified in class 530, subclass 350.
- II. Claims 10-12, drawn to a ligand which interacts with PrPsc, classified in class 530, subclass 350.
- III. Claims 10-12, drawn to a ligand which interacts with a factor that selectively interacts with PrPsc and not PrPc, classified in class 530, subclass 350.
- IV. Claims 13, drawn to a process for detecting PrPsc with the factor, classified in class 435, subclass 7.1.
- V. Claims 13, drawn to a process for detecting PrPsc with a ligand against PrPsc, classified in class 435, subclass 7.1.
- VI. Claims 14 and 17, drawn to a process for removing PrPsc with the factor, classified in class 530, subclass 400.
- VII. Claims 14 and 17, drawn to a process for removing PrPsc with the ligand against PrPsc, classified in class 530, subclass 400.

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- VIII. Claim 14 and 17, drawn to a process for removing PrPsc with ligand against the factor, classified in class 530, subclass 400.
- IX. Claims 15 and 16, drawn to a process for diagnosing disease with the factor, classified in class 435, subclass 7.1.
- X. Claims 15 and 16, drawn to a process for diagnosing disease with the ligand against PrPsc, classified in class 435, subclass 7.1.
- XI. Claims 15 and 16, drawn to a process for diagnosing disease with the ligand against the factor, classified in class 435, subclass 7.1.
- XII. Claim 17, drawn to a process for inactivating PrPc with the factor, classified in class 514, subclass 2.
- XIII. Claim 17, drawn to a process for inactivating PrPc with the ligand against the PrPsc, classified in class 514, subclass 2.
- XIV. Claim 17, drawn to a process for inactivating PrPc with the ligand against the factor, classified in class 514, subclass 2.

The inventions are distinct, each from the other because of the following reasons:

The factor of Invention I, the ligand that interacts with PrPsc of Invention II, and the ligand that interacts with the factor of Invention III differ in structure and function and are therefore patentably distinct one from the other.

Inventions I and Inventions IV, IX, and XII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions IV, IX, or XII.

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Inventions II and Inventions V, VII, X, and XIII are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions V, VII, X, and XIII.

Inventions III and Inventions VI, VIII, XI, and XIV are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the product as claimed can be used in a materially different process such as in any one of Inventions VI, VIII, XI, and XIV.

The product of Inventions I and II are not used in the methods of Inventions VI, VIII, XI, and XIV. Therefore, Inventions I and II are patentably distinct from Inventions VI, VIII, XI, and XIV.

The product of Inventions I and III are not used in the methods of Inventions V, VII, X, and XIII. Therefore, Inventions I and III are patentably distinct from Inventions V, VII, X, and XIII.

The product of Inventions II and III are not used in the methods of Inventions IV, IX, or XII. Therefore, Inventions II and III are patentably distinct from Inventions IV, IX, or XII.

The methods of Inventions IV through XIV require different products and steps and have different endpoints. Therefore, Inventions IV through XIV are patentably distinct.

Because these inventions are distinct for the reasons given above and have acquired a separate status in the art as shown by their different classification, restriction for examination purposes as indicated is proper.

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Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a petition under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Karen Cochrane Carlson, Ph.D. whose telephone number is 703-308-0034. The examiner can normally be reached on 7:00 AM - 4:00 PM, off alternate Fridays.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Christopher Low can be reached on 703-308-2329. The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for regular communications and 703-308-4242 for After Final communications.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-1235.

June 26, 2003



KAREN COCHRANE CARLSON, PH.D.
PRIMARY EXAMINER